

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

David Brown

Matthew Winkler

Group Art Unit: Unknown

Examiner: Unknown

Serial No.: Unassigned

Atty. Dkt. No.: AMBI:035USC1

Filed: Concurrently Herewith

For: METHODS AND COMPOSITIONS FOR  
STRIPPING NUCLEIC ACIDS

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NUMBER EL 780049582 US

DATE OF DEPOSIT February 25, 2002

PRELIMINARY AMENDMENT AND SPECIES ELECTION REQUIREMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicants respectfully submit this Preliminary Amendment and Species Election Requirement pursuant to the Species Election Requirement filed on September 30, 1998 in the parent case, Application Serial No. 08/907,195. Consideration of this case in view of the amendments made herein is respectfully requested.

## AMENDMENT

### In the Specification:

Please amend the specification as follows:

At page 2, line 2, please insert the following paragraph:

--This is a continuation of co-pending application Serial No. 08/907,195 filed August 6, 1997.--

### In the Claims:

Please cancel claims 36, 40, 44, and 46 without prejudice or disclaimer.

Please amend claim 33 as follows:

33. (Amended) A method of stripping a nucleic acid probe from a sample nucleic acid, said sample nucleic acid attached to a solid support, comprising:

- a) obtaining a solid support with a sample nucleic acid attached thereto;
- b) obtaining a nucleic acid probe, said nucleic acid probe comprising at least a first bond;
- c) admixing said nucleic acid probe with said solid support to allow association of said nucleic acid probe with said sample nucleic acid;
- d) cleaving said first bond of said nucleic acid probe with iodine, a hydroxyl ion, an enzyme, a particular wavelength of light, or temperature; and
- e) removing said nucleic acid probe from said sample nucleic acid.

## STATUS OF THE CLAIMS

Claims 36, 40, 44, and 46 have been cancelled without prejudice or disclaimer. Claim 33 has been amended. Support for these amendments may be found in the specification, for example, at page 5, lines 23-24 and line 27; page 6, lines 1-2; and page 12, lines 14-15. Therefore, claims 1-35, 37-39, 41-43, 45, and 47 are presently pending. A copy of the amended

claims with editing indicia is attached as Exhibit A. A copy of the presently pending claims is attached as Exhibit B.

### SPECIES ELECTION

In the parent application to this case, Application Serial No. 08/907,195 filed August 6, 1997, a Species Election Requirement was issued, attached as Exhibit C. In response to the Species Election Requirement in the parent case, Applicants elected species 1 (methods for stripping nucleic acids using iodine and kit to same). Claims directed to species 1 were ultimately allowed in the parent case. In the present application, Applicants wish to prosecute generic claims to which Applicants believe they are entitled. However, in order to expedite the prosecution in this case, and if the Species Election Requirement from the parent case is applicable to the present application, Applicants respectfully elect species 3 (methods for stripping nucleic acids using enzymes and kit for same).

Claims 1-6, 18-32, 34, 40-43, 45, and 47 are generic to all species claimed in the present application. Applicants reserve the right to prosecute claims directed to non-elected species.

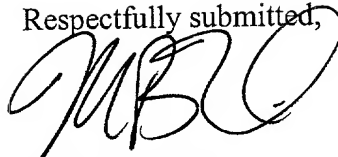
### CONCLUSION

While it is believed that no fees are occasioned by the filing this Preliminary Amendment and Species Election Requirement, should the Commissioner determine that any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required, the Assistant Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No. 50-1212/10200421/MBW.

The Examiner is invited to contact the undersigned attorney at (512) 536-3035 with any questions, comments or suggestions relating to the referenced patent application.

Please date stamp and return the enclosed postcard evidencing receipt of this paper.

Respectfully submitted,



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**APPENDIX A**  
**amended claims with editing indicia**

33. (Amended) A method of stripping a nucleic acid probe from a sample nucleic acid, said sample nucleic acid attached to a solid support, comprising:

- a) obtaining a solid support with a sample nucleic acid attached thereto;
- b) obtaining a nucleic acid probe, said nucleic acid probe comprising at least a first [phosphorothioate] bond;
- c) admixing said nucleic acid probe with said solid support to allow association of said nucleic acid probe with said sample nucleic acid;
- d) cleaving said [phosphorothioate] first bond of said nucleic acid probe with iodine, a hydroxyl ion, an enzyme, a particular wavelength of light, or temperature;  
and
- e) removing said nucleic acid probe from said sample nucleic acid. [; and
- f) admixing sodium thiosulfate with said solid support, thereby removing excess iodine from said solid support.]

**APPENDIX B**  
**presently pending claims**

1. A method of removing a nucleic acid probe from a sample nucleic acid comprising:
  - a) obtaining a sample nucleic acid associated with a nucleic acid probe;
  - b) breaking at least a first bond of the nucleic acid probe; and
  - c) removing the nucleic acid probe from said sample nucleic acid.
2. The method of claim 1, wherein said nucleic acid probe comprises DNA.
3. The method of claim 1, wherein said nucleic acid probe comprises RNA.
4. The method of claim 1, wherein said nucleic acid probe comprises at least a first uracil residue.
5. The method of claim 1, wherein said first bond is a phosphodiester bond.
6. The method of claim 1, wherein said first bond is a phosphorothioate bond.
7. The method of claim 6, wherein said first bond is broken by iodine.

8. The method of claim 7, wherein the concentration of said iodine is between about 0.1 mM and about 25 mM.

9. The method of claim 1, wherein said first bond is broken by a hydroxyl ion.

10. The method of claim 9, wherein the concentration of said hydroxyl ion is between about  $10^{-1}$  M and about  $10^{-5}$  M.

11. The method of claim 1, wherein said first bond is broken by an enzyme.

12. The method of claim 11, wherein said first bond is broken by uracil DNA glycosylase.

13. The method of claim 11, wherein said first bond is broken by a ribonuclease.

14. The method of claim 13, wherein said first bond is broken by inosine ribonuclease.

15. The method of claim 11, wherein said first bond is broken by a deoxyribonuclease.

16. The method of claim 1, wherein said first bond is broken by light.

17. The method of claim 1, wherein said first bond is broken by temperature.
18. The method of claim 1, wherein said sample nucleic acid comprises DNA.
19. The method of claim 1, wherein said sample nucleic acid comprises RNA.
20. The method of claim 1, comprising attaching said sample nucleic acid to a solid support.
21. The method of claim 20, wherein said solid support is a membrane.
22. The method of claim 21, wherein said membrane is a nitrocellulose membrane or a nylon membrane.
23. The method of claim 20, wherein said solid support is a resin.
24. The method of claim 23, wherein said resin is an ion exchange chromatography resin or an affinity chromatography resin.
25. The method of claim 30, wherein said solid support is plastic.
26. The method of claim 20, wherein said solid support is a magnetic bead.



27. The method of claim 20, wherein said solid support is glass.
28. The method of claim 20, wherein said solid support is a microchip.
29. The method of claim 20, comprising separating said sample nucleic acid by electrophoresis prior to attachment to said solid support.
30. The method of claim 29, comprising cleaving said sample nucleic acid by an enzyme prior to separation by electrophoresis.
31. The method of claim 1, wherein obtaining a sample nucleic acid associated with a nucleic acid probe comprises:
- a) obtaining a sample nucleic acid;
  - b) obtaining a nucleic acid probe; and
  - c) admixing said nucleic acid probe with said sample nucleic acid to allow association of said nucleic acid probe with said sample nucleic acid.
32. The method of claim 31 comprising attaching the sample nucleic acid to a solid support prior to admixing the nucleic acid probe with the sample nucleic acid.

33. A method of stripping a nucleic acid probe from a sample nucleic acid, said sample nucleic acid attached to a solid support, comprising:

- a) obtaining a solid support with a sample nucleic acid attached thereto;
- b) obtaining a nucleic acid probe, said nucleic acid probe comprising at least a first bond;
- c) admixing said nucleic acid probe with said solid support to allow association of said nucleic acid probe with said sample nucleic acid;
- d) cleaving said first bond of said nucleic acid probe with iodine, a hydroxyl ion, an enzyme, a particular wavelength of light, or temperature; and
- e) removing said nucleic acid probe from said sample nucleic acid.

34. A kit for removing a nucleic acid probe from a sample nucleic acid, comprising in a suitable container a compound that breaks at least a first bond of said nucleic acid probe.

35. The kit of claim 34, wherein said compound is a chemical.

37. The kit of claim 34, wherein said compound is an enzyme.

38. The kit of claim 37, wherein said enzyme is uracil DNA glycosylase.

39. The kit of claim 34, further comprising at least a first cleavable nucleotide for incorporation into said nucleic acid probe.

41. The kit of claim 39, wherein said cleavable nucleotide is a uracil nucleotide.

42. The kit of claim 39, wherein said cleavable nucleotide is an inosine nucleotide.

43. A kit for removing a nucleic acid probe from a sample nucleic acid, comprising, in a suitable container:

- a) probe degradation buffer; and
- b) reconstitution buffer.

45. The kit of claim 43, wherein said kit further comprises, in one or more suitable containers:

- a) at least a first cleavable ribonucleotide triphosphate;
- b) a nucleotide mixture; and
- c) a nucleotide polymerase;

47. A kit for detecting the association of a nucleic acid probe with a sample nucleic acid, comprising in a suitable container a solid support and a compound that breaks at least a first bond of said nucleic acid probe.

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1. This application contains claims directed to the following patentably distinct species of the claimed invention:

- (1) Method for stripping nucleic acids using iodine and kit to same;
- (2) Method for stripping nucleic acids using hydroxide ion and kit for same;
- (3) Method for stripping nucleic acids using enzymes and kit for same.
- (4) Method for stripping nucleic acids using light and kit for same.
- (5) Method for stripping nucleic acids using temperature and kit for same.

2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6, 18-32, 34, 40-43, 45 and 47 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit

Art Unit: 1623

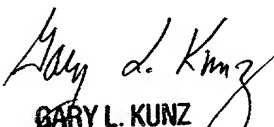
on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marion Knode, can be reached on (703) 308-4311. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
GARY L. KUNZ  
PRIMARY EXAMINER  
GROUP 1200